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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/535,763 | 05/20/2005 | Stefan Werner | 049202/289226 | 9269 |

826 7590 10/18/2007
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| EXAMINER |
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PAGE, BRENT T

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| ART UNIT | PAPER NUMBER |
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1638

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10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/535,763 | Applicant(s) WERNER ET AL. | |
| | Examiner Brent Page | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants election with traverse of Group I is hereby acknowledged. However, in order to clarify the invention, a supplemental restriction is set forth below. The traversal by Applicant will be addressed after the election of a Group set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 (in part), 9-31, drawn to a method of controlling a genetically modified organism, the genetically modified organism, and a system of controlling expression of a protein, wherein said protein has a segment that is capable of causing said expression of said protein.

Group II, claims 1-6(in part), 7-31, drawn to a method of controlling a genetically modified organism, the genetically modified organism, and a system of controlling expression of a protein, wherein said protein has a segment that is capable of controlling said cellular process.

Group III, claim(s) 32-34, drawn to A composition for external application to a multi-cellular organism.

The inventions are independent or distinct, each from the other because:

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims are related by the technical feature of a protein that is a signal for causing expression of a protein, this feature is not special since it does not constitute an advance over the prior art. Fitchen et al (WO 9521248) teach an MP protein that is

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applied exogenously to facilitate protein expression and cell to cell movement in a multi-cellular organism (see claims, for example).

Furthermore, each Group has functions and components that the other does not require and may be used for different processes and in different applications.

For example, the composition of Group III may be used as a protein supplement to a food for example, or it may be used in a yeast two-hybrid system to identify bound proteins, and does not need to be used with the methods of group I or Group II.

Likewise the Methods of Group I and II can use a different signal peptide than that used of Group III.

Additionally the method of Group I does not require the DNA or RNA modifying activity or the enzymes required by the method of Group II.

For the reasons given above, the two groups are independent and distinct and restriction is therefore proper.

In addition to the restriction requirement set forth above, Applicant, should they select Group I or Group II is also required to choose whether the protein portion is a viral coat protein, plant, animal or artificial protein portion as set forth in claims 19-22, and select only ONE origin for the peptide thusly claimed for examination. Applicants also must select ONE external signal that causes expression, either small molecular organic compound OR, metal ions, OR a polypeptide, OR a protein, OR a nucleic acid, OR a pathogen, OR a virus, OR a bacterium, OR a fungus, OR light OR temperature change. Should Applicants select polypeptide from this group, Applicants also must select only ONE pathogenic microorganism for application of polypeptide either virulent

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Agrobacterium, non-virulent Agrobacterium, virulent bacteria with type-III secretion signal, non-virulent bacteria with type-III secretion signal OR ONE of virulent or non-virulent Bordetella, Erwinia, OR Pseudomonas, OR Xanthomonas, OR Yersinia.

Applicant also must select ONE type of transformation, either stable integration into genome, OR stable integration into plastid, OR transient transformation. Applicant further must indicate which claims are believed to read on the elected Invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

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RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

Russell P. Kallis